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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Mutant IDH1 Inhibitors Useful for Treating Cancer

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Center for Advancing Translational Sciences, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the Supplementary Information section of this Notice to Platform Pharmaceuticals, Inc. ("Platform Pharma"), headquartered in New York, NY**.**

DATES: Only written comments and/or applications for a license which are received by the National Center for Advancing Translational Sciences' Office of Strategic Alliances on or before [INSERT DATE 15 DAYS FROM DATE OF PUBLICATION OF NOTICE IN THE FEDERAL REGISTER] will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, and comments relating to the contemplated Exclusive Patent License should be directed to: Sury Vepa, Ph.D., J.D., Senior Licensing and Patenting Manager, Office of Strategic Alliances, Telephone: (301)-642-0460; E-mail: sury.vepa@nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

1. U.S. Provisional Patent Application No. 62/095,322 filed on 12/22/2014 which is entitled "Mutant IDH1 Inhibitors Useful for Treating Cancer" (HHS Ref. No. E-243-2014-0-US-01);

2. International Patent Application No. PCT/US2015/067406 filed on 12/22/2015 which is entitled “Mutant IDH1 Inhibitors Useful for Treating Cancer” (HHS Ref. No. E-243-2014-0-PCT-02);

3. Australian Patent Application No. 2015369712 filed on 12/22/2015 which is entitled “Mutant IDH1 Inhibitors Useful for Treating Cancer” which was issued as Patent No. 2015369712 on 8/20/2020 (HHS Ref. No. E-243-2014-0-AU-03);

4. Canadian Patent Application No. 2971872 filed on 12/22/2015 which is entitled “Mutant IDH1 Inhibitors Useful for Treating Cancer” (HHS Ref. No. E-243-2014-0-CA-04);

5. Chinese Patent Application No. 2015800763284 filed on 12/22/2015 which is entitled “Mutant IDH1 Inhibitors Useful for Treating Cancer” which was issued as Patent No. ZL2015800763284 on 4/13/2021” (HHS Ref. No. E-243-2014-0-CN-05);

6. European Patent Application No. 15823901.2 filed on 12/22/2015 which is entitled “Mutant IDH1 Inhibitors Useful for Treating Cancer” which issued as Patent No. 3237385 on 11/24/2021 and validated in Germany, Spain, France, Great Britain, and Italy (HHS Ref. No. E-243-2014-0-EP-06);

7. Japanese Patent Application No. 2017534314 filed on 6/22/2017 which is entitled “Mutant IDH1 Inhibitors Useful for Treating Cancer” which was issued as Patent No. 6901394 on 6/21/2021 (HHS Ref. No. E-243-2014-0-JP-07);

8. U.S. Patent Application No. 15/538,570 filed on 12/12/2015 which is entitled “Mutant IDH1 Inhibitors Useful for Treating Cancer” which issued as Patent No. 10,703,746 on 7/7/2020 (HHS Ref. No. E-243-2014-0-US-08);

9. U.S. Provisional Patent Application No. 62/353,298 filed on 6/22/2016 which is entitled “Mutant IDH1 Inhibitors Useful for Treating Cancer” (HHS Ref. No. E-189-2016-0-US-01);

10. International Patent Application No. PCT/US2017/038549 filed on 6/21/2017 which is entitled “Mutant IDH1 Inhibitors Useful for Treating Cancer” (HHS Ref. No. E-189-2016-0-PCT-02);

11. Australian Patent Application No. 2017281088 filed on 6/21/2017 which is entitled “Mutant IDH1 Inhibitors Useful for Treating Cancer” which was issued as Patent No. 2017281088 on 9/9/2021 (HHS Ref. No. E-189-2016-0-AU-04);

12. Canadian Patent Application No. 3028999 filed on 6/21/2017 which is entitled “Mutant IDH1 Inhibitors Useful for Treating Cancer” (HHS Ref. No. E-189-2016-0-CA-05);

13. Chinese Patent Application No. 2017800514100 filed on 6/21/2017 which is entitled “Mutant IDH1 Inhibitors Useful for Treating Cancer” which was issued as Patent No. 201780051410.0 on 9/20/2022 (HHS Ref. No. E-189-2016-0-CN-06);

14. European Patent Application No. 17735296.0 filed on 6/21/2017 which is entitled “Mutant IDH1 Inhibitors Useful for Treating Cancer” which issued as

Patent No. 3475276 on 3/31/2021 and validated in Germany, Spain, France, Great Britain, and Italy (HHS Ref. No. E-189-2016-0-EP-07);

15.. Japanese Patent Application No. 2018-567108 filed on 6/21/2017 which is entitled "Mutant IDH1 Inhibitors Useful for Treating Cancer" which was issued as Patent No. 6987798 on 12/3/2021(HHS Ref. No. E-189-2016-0-JP-08); and

16.. U.S. Patent Application No. 16/312,206 filed on 12/20/2018 which is entitled "Mutant IDH1 Inhibitors Useful for Treating Cancer" which was issued as Patent No. 10,836,759 on 11/17/2020 (HHS Ref. No. E-189-2016-0-US-03).

The patent rights in these inventions have been either assigned and/or exclusively licensed to the government of the United States of America and the University of North Carolina at Chapel Hill.

The prospective exclusive license territory may be worldwide, and the field of use may be limited to the following:

"Use of mutant isocitrate dehydrogenase 1 (mIDH1) inhibitors, as claimed in the licensed patent rights, for the treatment of cancers (such as acute myeloid leukemia, glioma, cholangiocarcinoma, glioblastoma multiforme (GBM) and other solid tumors) and rare diseases."

The inventions relate to a series of novel compounds that potently and selectively inhibit mIDH1. These compounds reduce 2–HG levels in cell lines in vitro as well as in human cancer cells grown in mouse xenografts in vivo.

These compounds show greater than 250-fold selectivity for the mutant enzyme over the wild-type, show favorable in vitro stability (in mouse, rat, dog and human hepatocyte exposure studies), are AMES negative, and exhibit no significant metabolic CYP liabilities. These compounds possess very favorable in vivo rodent pharmacokinetics and bioavailability and are well tolerated in rodents, even when dosed at high levels.

Thus, the compounds of the subject inventions can be used individually or in combination to develop new therapies to treat diseases which result from mutant IDH1 activity. The diseases caused by mutant IDH1 activity include cancer (e.g., acute myeloid leukemia, glioma, cholangiocarcinoma and potentially other solid tumors) and selected rare diseases, such as Ollier Disease.

This Notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published Notice, the National Center for Advancing Translational Sciences receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information from these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 U.S.C. 552.

Joni L. Rutter,

Director, Office of the Director,

National Center for Advancing Translational Sciences.

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